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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,717	DUNMORE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-19) in the reply filed on 10/27/06 is acknowledged. It is noted that nonelected claims 20-22 have been cancelled.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,763,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sole difference between claims 1-3, 5, 7-11, 13, 15, 16 & 18 of the instant invention and those patented in '200 is that claims 1-3, 5 & 7 are incorporated into base claim 1 of '200, etc. In regards to claims 4, 6, 12 14, 17 & 19, any cell that reasonably expresses the SSTR-5 receptor is

an obvious source for SSTR-5 for use in any competition assay for identifying compounds that compete with ligand binding to SSTR-5 (i.e., as it relates to alternatively using rat olfactory bulb preps as the source for SSTR-5). Likewise, use of any pancreatic-derived cell well known in the art that secretes amylin is an obvious source for the amylin release component in the recited method (i.e., as it relates to us of amylinoma cells and/or RINm5f cells).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 7-11, 13, 15-16 & 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Inoue et al. (IDS Ref #I) or Moore et al. (IDS Ref #J), in view of Yamada et al. (IDS Ref #O).

Inoue et al. teach a method of determining the ability of a compound (i.e., somatostatin, which by definition binds to the somatostatin type-5 receptor) to inhibit amylin release from amylin-secreting rodent pancreas cells (i.e., as it relates to claims 1-2, 10-11, 13, 15-16 & 18). The pancreatic cells are incubated with the amylin release stimulators, glucose or arginine, under

conditions in which amylin secretion is induced, followed by addition of somatostatin, in which amylin secretion is then inhibited by 40-70% (pg. 251, Abstract and pg. 252, Figure 1A and Table 1). However, Inoue et al. do not teach determining the ability of a compound to compete against ligand binding to SSTR-5, in which at least the ligand or compound (i.e., agonist) is detectably labeled.

Moore et al. teach a method of determining the ability of a compound (i.e., somatostatin, which by definition binds to the somatostatin type-5 receptor) to inhibit amylin release from amylin-secreting pancreas cells (i.e., HIT T15 β-islet cells; as it relates to claims 1-2 & 10-11). The pancreatic cells are incubated with the amylin release stimulators, glucose plus arginine, under conditions in which amylin secretion is induced, followed by addition of somatostatin, in which amylin secretion is subsequently inhibited by 40% (pgs. 5-6 and Figure 5B). However, Moore et al. do not teach determining the ability of a compound to compete against ligand binding to SSTR-5, in which at least the ligand or compound (i.e., agonist) is detectably labeled.

Yamada et al. teach a method for obtaining preparations containing SSTR-5 that are used to determine the ability of compounds to bind to SSTR-5 (i.e., the first step of the method of claim 1). The rank potency of somatostatin analogs are: somatostatin-28>somatostatin-14 >>RC-160>SMS201-995 for human SSTR-5, based on competition studies (pg. 844, Abstract). Yamada further teach that after obtaining a preparation of cell membranes (i.e., as it relates to claims 1 & 3), which contains SSTR-5 (i.e., COS1 cells expressing SSTR-5; as it relates to the equivalent transfected cells of claims 5 & 7), incubation with a detectably labeled ligand (i.e., [^{125}I-Tyr^{11}]- somatostatin-14; as it relates to claims 8-9) in the presence of the compounds somatostatin-14, somatostatin-28, SMS201-995 and RC-160 compete against labeled somatostatin-14 for binding to SSTR-5. However, Yamada do not teach obtaining amylin-secreting pancreatic cells in their method (i.e., the second step of claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to use the method of Yamada et al. for determining binding compounds for SSTR-5, followed by evaluation of the biological effects of SSTR-5 compounds using the method of Moore or Inoue to inhibit amylin secretion in pancreatic cells, because agonists have similar functional activities as native ligands by definition, and because Yamada specifically suggest that use of somatostatin subtypes (e.g., SSTR-5 agonists) should reveal the molecular basis for somatostatin function, which includes exocrine and endocrine function (i.e., amylin inhibition) in the pancreas, pituitary and GI tract (see pgs. 851 and 845).

4. Claims 1-11, 13, 15-16 & 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Inoue et al. or Moore et al., in view of Yamada et al., as applied to claims 1-3, 5, 7-11, 13, 15-16 & 18 above, and further in view of Hoyer et al. (IDS Ref #H).

Inoue et al., Moore et al. and Yamada et al. are as described above. However, none of these three references teach that rodent olfactory bulb contain SSTR-5 receptors.

Hoyer et al. teach numerous sources for cell preparations that contain SSTR-5 in Table 3 (pg. 447) that includes rat olfactory bulb (as it relates to claims 4 & 6), as well as CHO-K1 cells transfected with SSTR-5 (pgs. 444-445 and Fig. 2; as it relates to claims 5 & 7). However, Hoyer do not specifically teach subsequent inhibition of amylin secretion in pancreatic cells, even though they do disclose that somatostatin inhibits the pancreatic-associated hormones insulin and glucagon with different pharmaceutical profiles (pg. 441, 2nd column).

It would have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to use Hoyer's cell preparations (i.e., rat olfactory bulb and CHO-K1/SSTR-5 cells; as it relates to claims 4-7), or Hoyer's somatostatin agonists (pg. 443, Table 2) in the method of Yamada as described above, because different tissues express different levels of SSTR-5 and thus provides an additional source of cell/membrane preparations for carrying out

Yamada's method using competing SSTR-5 binding compounds when combined with the methods of Inoue or Moore for inhibiting amylin secretion, as discussed above.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
January 9, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER